REMARKS

Claims 1-6 and 8 are pending.

Claims 1-3 have been amended to reflect the subject matter of the restriction group elected.

Claim 6 has been amended to clearly indicate that the compound used in the method further comprises a pharmaceutically acceptable carrier.

No new matter has been added.

Claim Objections

The Examiner has objected to claims 1-3, 5, 6 and 8 for containing non-elected subject matter. Applicants have amended the claims to reflect the restriction group elected, thereby overcoming the objection.

The Examiner also states "Claim 7 objected to because of the following informality." Applicants note that claim 7 was canceled in a preliminary amendment in 2005. Applicants assume that the Examiner is referring to claim 6, which addresses pharmaceutically acceptable carriers. Claim 6 has been amended to correct the informality, thereby overcoming the objection.

Rejections Under 35 USC § 112, first paragraph

The Examiner has rejected claims 1-3, 5, 6 and 8 for lack of enablement. The Examiner contends that the compounds within the Markush claim are "not supported by the disclosure (i.e. species not reduced to practice)." It would appear that the Examiner's analysis hinges on the fact that not all of the compounds have been reduced to practice. But reduction to practice is not required. The MPEP states in section 2164.02 "An applicant need not have actually reduced the invention

to practice prior to filing." The courts have also ruled that prophetic examples (i.e. those not actually reduced to practice) are not automatically non-enabled. *Atlas Powder Company v E.I. DuPont De Nemours & Company*, 224 USPQ 409, 414 (CAFC 1984).

Applicants also traverse the Examiner's *Wands* analysis. In *In re Wands* the court found enablement, stating that the Specification provided considerable direction and guidance on how to practice the claimed invention, that all of the methods needed to practice the invention were well known and that there was a high level of skill in the art at the time the application was filed. In the present case the Examiner acknowledges that the ordinary skill in the art is high (see page 5 of the Office Action), yet again states "direction and working examples are limited to the compounds reduced to practice" (see page 6) and concludes that undue experimentation is needed to practice the invention because "it is not known which of the unrepresented compounds meet the structural requirements for activity" (page 6). Again the Examiner is improperly focused on the lack of actual reduction to practice of each of the claimed compounds.

The Examiner has chosen to ignore the disclosure in the Specification on page 7, line 28 to page 9, line 14 which provides a summary of the methods used to distinguish and test the claimed compounds and provides citations for the scientific papers that give the details of the testing methods (i.e. W.J. Ming et al. (1987) J Immunol 138:1469; W. Falket et al. (1980) J Immunol Methods 33:239; C. Bizzarri et al. (1995) Blood 86:2388 and J.H. Liu et al. (1992) J Infect Dis 166:1089). The fact that experimentation is required is not problematic and the *In re Wands* court has stated that even a considerable amount of experimentation is permissible if the experimentation is routine. Here, Applicants are using standard and well known screening techniques reported in the scientific literature. Thus, such experimentation as is required to test additional compounds within the scope of the claims for activity is routine, and not "undue.

The Examiner has also based her enablement rejection on her allegations that the compounds may not inhibit IL-8 and that undue experimentation would be required because there is not an art recognized correlation between IL-8 inhibition and treatment of the claimed diseases. But again, the Examiner is ignoring significant disclosure in the Specification. The Specification

states that psoriasis, rheumatoid arthritis, ulcerative cholitis, acute respiratory distress syndrome (ARDS), idiopathic fibrosis, glomerulonephritis and bollous pemphigo are correlated with IL-8 inhibition (see the references cited on page 9, line 29 to page 10, line 8). For example, inhibition of IL-8 is suggested as a treatment for rheumatoid arthritis by Seitz *et al.* (see page 468) and has also been recognized by the EPO (see European Patent EP0894501). Page 1808 in Nickoloff *et al.* states "in the present study, the IL-8 gene expression by alveolar macrophages from the IPF and IPT-CTD patients studied appears to be specifically related to disease and not to some other exogenous stimulus." In addition, inhibition of IL-8 as a model for treatment of ulcerative cholitis has been recognized by the USPTO (see US 5,707,622); inhibition of IL-8 is also recognized as a model for prevention of ARDS (see Mukaida et al. (1998) Inflammation Research 47:151-157); inhibition of IL-8 is further recognized by the USPTO as treatment for glomerulonephritis (see US 5,707,621) and IL-8 inhibition is recognized as the mechanism of action for treatment of bullous pemphigoid by dapsone (see Schmidet et al. (2001) Clin Exp Immunol 124:157-162. Consequently, the teachings in the instant application do, indeed, present the correlation between IL-8 and the claimed disease treatments.

All of the above indicate that Applicants have met their burden to provide sufficient information regarding the subject matter of the claims as to enable one skilled in the art to make and use the claimed invention. No undue experimentation is required. Consequently, Applicants respectfully request reconsideration and removal of the rejections.

Conclusion

In view of the above remarks, all the claims remaining in the case as amended are submitted as defining non-obvious, patentable subject matter. Reconsideration of the rejections and allowance of the claims are respectfully requested.

If the Examiner has any questions concerning this application, the Examiner is requested to contact the Susan W. Gorman at 858-792-8855 in San Diego, California to expedite examination of the application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to our Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. § 1.16 or under § 1.17; particularly, extension of time fees.

Dated: April 4, 2008

Respectfully submitted,

#47,604

By _____
Mark J. Nuell, Ph.D.
Registration No.: 36,623
BIRCH, STEWART, KOLASCH & BIRCH, LLP
8110 Gatehouse Road
Suite 100 East
P.O. Box 747
Falls Church, Virginia 22040-0747
(858) 792-8855
Attorney for Applicant

Enclosures: Liu et al. 1992
Mahida et al. 1992
Wada et al. 1994
Miller et al. 1992